

TYPES OF EXCIPIENTS

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Antiadherents:

Antiadherents are used to reduce the adhesion between the powder (granules) and the punch faces and thus prevent sticking to tablet punches. They are also used to help protect tablets from sticking. Most commonly used is magnesium stearate.

Binders:

Binders hold the ingredients in a tablet together. Binders ensure that tablets and granules can be formed with required mechanical strength, and give volume to low active dose tablets. Binders are usually:

- Saccharides and their derivatives:
 - Disaccharides: sucrose, lactose;
 - Polysaccharides and their derivatives: starches, cellulose or modified cellulose such as microcrystalline cellulose and cellulose ethers such as hydroxypropyl cellulose (HPC);
 - Sugar alcohols such as xylitol, sorbitol or maltitol;
- Protein: gelatin;
- Synthetic polymers: polyvinylpyrrolidone (PVP), polyethylene glycol (PEG)...

Binders are classified according to their application:

- Solution binders are dissolved in a solvent (for example water or alcohol can be used in wet granulation processes). Examples include gelatin, cellulose, cellulose derivatives, polyvinylpyrrolidone, starch, sucrose and polyethylene glycol.
- Dry binders are added to the powder blend, either after a wet granulation step, or as part of a direct powder compression (DC) formula. Examples include cellulose, methyl cellulose, polyvinylpyrrolidone and polyethylene glycol.

Coatings:

Tablet coatings protect tablet ingredients from deterioration by moisture in the air and make large or unpleasant-tasting tablets easier to swallow. For most coated tablets, a cellulose ether hydroxypropyl methylcellulose (HPMC) film coating is used which is free of sugar and potential allergens. Occasionally, other coating materials are used, for example synthetic polymers, shellac, corn protein zein or other polysaccharides. Capsules are coated with gelatin.

➤ **Changing the dissolution rates of active species:**

Enterics control the rate of drug release and determine where the drug will be released in the digestive tract

Disintegrants:

Disintegrants expand and dissolve when wet causing the tablet to break apart in the digestive tract, releasing the active ingredients for absorption. They ensure that when the tablet is in contact with water, it rapidly breaks down into smaller fragments, facilitating dissolution.

Examples of disintegrants include:

- Crosslinked polymers: crosslinked polyvinylpyrrolidone (crospovidone), crosslinked sodium carboxymethyl cellulose (croscarmellose sodium).
- The modified starch sodium starch glycolate.

Fillers:

Fillers fill out the size of a tablet or capsule, making it practical to produce and convenient for the consumer to use. By increasing the bulk volume, the fillers make it possible for the final product to have the proper volume for patient handling. A good filler must be inert, compatible with the other components of the formulation, non-hygroscopic, relatively cheap, compactible, and preferably tasteless or pleasant tasting. Plant cellulose (pure plant filler) is a popular filler in tablets or hard gelatin capsules. Dibasic calcium phosphate is another popular tablet filler. A range of vegetable fats and oils can be used in soft gelatin capsules.

Other examples of fillers include: *lactose, sucrose, glucose, mannitol, sorbitol, calcium carbonate, and magnesium stearate.*

Flavours:

Flavours can be used to mask unpleasant tasting active ingredients and improve the acceptance that the patient will complete a course of medication. Flavourings may be natural (e.g. fruit extract) or artificial.

For example, to improve:

- ✓ a bitter product - mint, cherry or anise may be used
- ✓ a salty product - peach, apricot or liquorice may be used
- ✓ a sour product - raspberry or liquorice may be used
- ✓ an excessively sweet product - vanilla may be used

Colours:

Colours are added to improve the appearance of a formulation. Colour consistency is important as it allows easy identification of a medication.

Lubricants:

Lubricants prevent ingredients from clumping together and from sticking to the tablet punches or capsule filling machine. Lubricants also ensure that tablet formation and ejection can occur with low friction between the solid and die wall. Common minerals like talc or silica, and fats, e.g. vegetable stearin, magnesium stearate or stearic acid are the most frequently used lubricants in tablets or hard gelatin capsules. Lubricants are agents added in small quantities to tablet and capsule formulations to improve certain processing characteristics.

There are three roles identified with lubricants as follows:

1. True Lubricant Role:

- *To decrease friction at the interface between a tablet's surface and the die wall during ejection and reduce wear on punches & dies.*

2. Anti-adherent Role:

- *Prevent sticking to punch faces or in the case of encapsulation, lubricants*
- *Prevent sticking to machine dosators, tamping pins, etc.*

3. Glidant Role:

- *Enhance product flow by reducing interparticulate friction.*

There are two major types of lubricants:

1. Hydrophilic

- Generally poor lubricants, no glidant or anti-adherent properties.

2. Hydrophobic

- Most widely used lubricants in use today are of the hydrophobic category. Hydrophobic lubricants are generally good lubricants and are usually effective at relatively low concentrations. Many also have both anti-adherent and glidant properties. For these reasons, hydrophobic lubricants are used much more frequently than hydrophilic compounds. Examples include magnesium stearate.

Glidants:

Glidants are used to promote powder flow by reducing interparticle friction and cohesion. These are used in combination with lubricants as they have no ability to reduce die wall friction. Examples include fumed silica, talc, and magnesium carbonate.

Sorbents:

Sorbents are used for tablet/capsule moisture-proofing by limited fluid sorbing (taking up of a liquid or a gas either by adsorption or by absorption) in a dry state. Materials used for enteric coatings include fatty acids, waxes, shellac, plastics, and plant fibers.

Preservatives:

Some typical preservatives used in pharmaceutical formulations are:

- Antioxidants like vitamin A, vitamin E, vitamin C, retinyl palmitate, and selenium
- The amino acids cysteine and methionine
- Citric acid and sodium citrate[disambiguation needed]
- Synthetic preservatives like the parabens: methyl paraben and propyl paraben.

Sweeteners:

Sweeteners are added to make the ingredients more palatable, especially in chewable tablets such as antacid or liquids like cough syrup. Sugar can be used to mask unpleasant tastes or smells.